

Message Text

UNCLASSIFIED

PAGE 01 STATE 310270
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 /022 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/OPT/BMP: WJWALSH, III
DHEW/OIH: BROYSTER
EA/ANP:HTNELSON(INFO)

-----232153Z 112033 /60

P 232053Z DEC 76
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
INFO AMCONSUL PERTH PRIORITY

UNCLAS STATE 310270

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS

SUBJECT: RECALL OF INTRAOCULAR IRIS PLANE LENS (RECALL
NO. T-019-7)

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED:

COPELAND INTRAOCULAR IRIS PLANE LENS FOR IMPLANTATION INTO
THE EYE TO REPLACE A CATARACT-DAMAGED LENS. EACH POLY-
METHYL METHACRYLATE LENS IS PACKED IN A SEALED GLASS VIAL
CONTAINING APPROXIMATELY 3 CC'S OF SODIUM BICARBONATE SOL-
UTION. FROM 1-3 VIALS ARE PACKED IN A PLASTIC SHIPPING
CASE WITH A LABELING INSERT. THREE DIFFERENT DIOPTRIC
POWERS ARE INVOLVED: 17.62, 19.00 AND 21.50 DIOPTRIC LENSES.

PRODUCT IDENTIFICATION:

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 310270

A. VIAL CONTAINING LENS IS LABELED "ONE INTRAOCULAR LENS -
STERILE - IN SODIUM BICARBONATE 5.0 PERCENT SOLUTION -
COPELAND INTRA LENSES INC., N.Y., N.Y. 10021". VIAL LABEL
ALSO LISTS LOT NUMBER OF LENS AND THE DIOPTRIC POWER. THE

PLASTIC SHIPPING CASE LABEL READS IN PART: "INTRAOCULAR

LENSES STERILE - IN SEALED CONTAINERXXXMADE BY COPELAND
INTRA LENSES INC., 129 EAST 61ST STREET, N.Y., N.Y. 10021".

B. EACH LENS, WHEN SHIPPED, IS ASSIGNED A LENS SERIAL
NUMBER WHICH IS ETCHED INTO THE VIAL CRIMP TOP AND WHICH
IS WRITTEN ON THE SHIPPING CASE. THE LOT NUMBER APPEARS
ONLY ON THE VIAL LABEL.

THE FOLLOWING LOT NUMBERS, LENS POWERS, AND LENS NUMBERS
INVOLVED IN THIS RECALL ARE AS FOLLOWS:

LOT NO. 76281; DIOPTER OF LENSES 17.61 AND 21.50; LENS
SERIAL NUMBERS 17-115762 AND HIGHER; LENS NO.'S 21-110761
AND HIGHER.

LOT NUMBER 76285; DIOPTER LENSES 17.61 AND 19.00; ALL LENS
SERIAL NUMBERS.

LOT NUMBER 76296; DIOPTER LENSES 19.00; ALL LENS SERIAL NU-
MBERS.

LOT NUMBER 76304; DIOPTER LENSES 19.00 AND 21.50; ALL LENS
SERIAL NUMBERS.

LOT NUMBER 76310; DIOPTER LENSES 19.00; ALL LENS SERIAL
NUMBERS.

MANUFACTURER/RECALLING FIRM:

COPELAND INTRA LENS INC.
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 310270

129 EAST 61ST STREET
NEW YORK CITY, NEW YORK 10021

COPELAND MANUFACTURED THE LENSES. THE LENSES WERE STER-
ILIZED AND PACKED INTO VIALS BY A CONTRACT FIRM: TORIGIAN
LABS, INC., 218-20 98TH AVENUE, QUEENS VILLAGE, NEW YORK,
N.Y. 11429.

2. REASON FOR RECALL:

OF THE 525 LENS UNDER RECALL OF THE 5 LOTS DISTRIBUTED,
COPELAND HAS DETERMINED THAT 29 HAVE BEEN IMPLANTED. TO
DATE COPELAND HAS RECEIVED 9 COMPLAINTS OF PSUEDOMONAS

INFECTIONS IN THE EYES OF THE PATIENTS WHO RECEIVED COPE-
LAND LENS IMPLANTS. COPELAND HAS INITIATED RECALL TO ALL

CONSIGNEES OF THE RECALLED LOTS BY PHONE CALL AND BY RECALL LETTERS. THE FIRM PLANS TO RSTERLIZE AND REPACK ALL RETURNS.

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF HE HAS RECEIVED RECALL LETTER FROM FIRM. THE FOREIGN CONSIGNEE IS:

IAN NORTH, M.D.
8 EMERALD TERRACE
WEST PERTH 6005
WEST AUSTRALIA

ANY QUESTION CONSIGNEE MAY HAVE WITH RESPECT TO THIS RECALL SHOULD BE DIRECTED TO MR. MICHAEL J. COPELAND, PRESIDENT, COPELAND INTRA LENS, INC., 129 E. 61ST STREET, NEW YORK CITY, N.Y. 10021.
KISSINGER
UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 310270

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL CARE, EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 23 DEC 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE310270
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760471-0560
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19761216/aaaaangg.tel
Line Count: 139
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: vogelfj
Review Comment: n/a
Review Content Flags:
Review Date: 15 JUN 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <15 JUN 2004 by chengls>; APPROVED <20 DEC 2004 by vogelfj>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF INTRAOCULAR IRIS PLANE LENS (RECALL NO. T-019-7)
TAGS: OGEN, ETRD, EIND, TBIO, AS
To: CANBERRA
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006